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November 11, 1999

## BOX PATENT APPLICATION

## SMALL ENTITY

Honorable Commissioner of  
Patents and Trademarks  
Washington, D.C. 20231

Re: Application of Gisela MEIER, Heinrich PAJUNK  
and Horst PAJUNK  
"CONTINUOUSLY CONDUCTIVE UNIPOLAR CANNULA FOR ANESTHESIA"  
Our Ref.: 2368/098

Dear Sir:

Attached hereto is the application identified above including the German-language specification, claims and abstract; English-language translation and Verification Statement; three (3) sheets of drawings; and Preliminary Amendment. The Declaration and Power of Attorney and Small Entity Declaration will be filed in the near future.

The Government filing fee is calculated as follows:

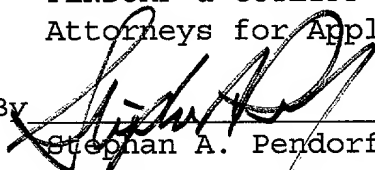
Total claims .....	11	- 20 =	_____	x \$ 9 =	\$
Independent Claims .....	1	- 3 =	_____	x \$39 =	\$
Declaration late filing fee.....	\$ 65.00				
Base Fee .....	\$380.00				
TOTAL FILING FEE .....				\$445.00	

Attorney Docket: 2368.098

A check for the statutory filing fee of \$445.00 is attached. Please charge or credit any difference or overpayment to Deposit Account No. 16-0877. The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §1.16 and §1.17 which may be required during the entire pendency of the application to said Account.

Respectfully submitted,

PENDORF & CUTLIFF  
Attorneys for Applicants

By   
Stephan A. Pendorf  
Registration No. 32,665

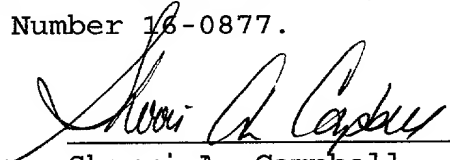
EXPRESS MAIL CERTIFICATE

"EXPRESS MAIL" MAILING LABEL NUMBER: EL435909438US

DATE OF DEPOSIT: November 11, 1999

I HEREBY CERTIFY that the foregoing cover letter including the German-language specification, claims and abstract; English-language translation and Verification Statement; three (3) sheets of drawings; and Preliminary Amendment and a stamped receipt post card are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated and is addressed: ATTN: Patent Application, Commissioner of Patents and Trademarks, Washington, D.C. 20231.

The Commissioner is hereby authorized to charge any additional fees which may be required at any time during the prosecution of this application without specific authorization, or credit any overpayment, to Deposit Account Number 16-0877.

  
Sherri A. Campbell

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Gisela MEIER, Heinrich PAJUNK and Horst PAJUNK

Appln. No.:

Filed: November 11, 1999

For: CONTINUOUSLY CONDUCTIVE UNIPOLAR CANNULA FOR ANESTHESIA

Attorney Docket No.: 2368.098

PRELIMINARY AMENDMENT

ATTN: PATENT APPLICATION  
Honorable Commissioner of  
Patents and Trademarks  
Washington, D.C. 20231

Sir:

Prior to examination of the above-identified application,  
please amend the application as follows:

IN THE SPECIFICATION:

Page 1, line 2, insert:

--BACKGROUND OF THE INVENTION

Field of the Invention--

Page 1, line 5, insert:

--Description of the Relate Art--

Page 2, line 20, insert:

--SUMMARY OF THE INVENTION--

Page 2, delete the third full paragraph (lines 27-28) in its  
entirety.

Page 3, delete the first full paragraph (lines 1-2) in its entirety.

Page 5, before line 1, insert:

--BRIEF DESCRIPTION OF THE DRAWINGS--

Page 5, line 14, insert:

--DETAILED DESCRIPTION OF THE INVENTION--.

IN THE CLAIMS:

Page 11, line 1, please delete "Patent Claims" and insert therefore --What is claimed is:--

Claim 2, lines 1-2, delete "thereby characterized, that" and insert --wherein--;

Claim 3, lines 1-2, delete "thereby characterized, that" and insert --wherein--;

Claim 4, lines 1-2, delete "one of claims 1-3, thereby characterized, that" and insert --claim 1, wherein--;

Claim 5, lines 1-2, delete "one of the preceding claims, thereby characterized, that" and insert --claim 1, wherein--;

Claim 6, lines 1-2, delete "one of the preceding claims, thereby characterized, that" and insert --claim 1, wherein--;

Claim 7, lines 1-2, delete "one of preceding claims, thereby characterized, that" and insert --claim 1, wherein--;

Claim 8, lines 1-2, delete "one of claims 1-7, thereby characterized, that" and insert --claim 1, wherein--;

Claim 9, lines 1-2, delete "thereby characterized, that" and

U.S. Application No.:  
PRELIMINARY AMENDMENT

Attorney Docket: 2368/098

insert --claim 1, wherein--;

Claim 10, lines 1-2, delete "one of claims 1-7, thereby characterized, that" and insert --claim 1, wherein--; and

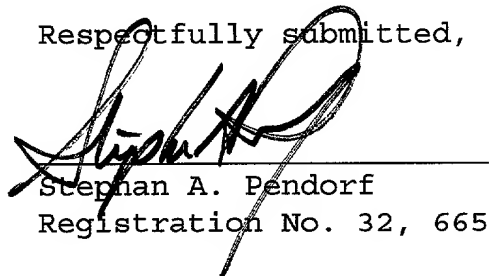
Claim 11, lines 1-2, delete "thereby characterized, that" and insert --wherein--.

REMARKS

The specification claims have been amended to conform the original translated specification and claims to U.S. requirements, i.e., appropriate section headers are added, reference in the specification to the claims have been amended in order to eliminate multiple dependent claims and claims improperly depending from multiple dependent claims, and to otherwise conform the claims to U.S. practice. Care has been taken to ensure that no new matter is added to the text.

Entry and favorable consideration prior to consideration are respectfully requested.

Respectfully submitted,



Stephan A. Pendorf  
Registration No. 32, 665

PENDORF & CUTLIFF  
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Date: November 11, 1999

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Gisela MEIER, Heinrich PAJUNK and Horst PAJUNK

Appln. No.:

Filed: November 11, 1999

For: CONTINUOUSLY CONDUCTIVE UNIPOLAR CANNULA FOR ANESTHESIA

Attorney Docket No.: 2368.098

VERIFICATION STATEMENT PURSUANT TO 37 C.F.R. §1.68

ATTN: PATENT APPLICATION  
Honorable Commissioner of  
Patents and Trademarks  
Washington, D.C. 20231

Sir:

I, Stephan A. Pendorf, declare and state the following:

I am a citizen of the United States residing at 3940  
Venetian Way, Tampa, Florida;

I have lived in Germany for 14 years and am familiar with  
both the German and English languages and have experience as a  
technical translator;

The attached English-language document is a full, true and  
faithful translation made by me of the text of the attached

U.S. Application No.:  
VERIFICATION STATEMENT

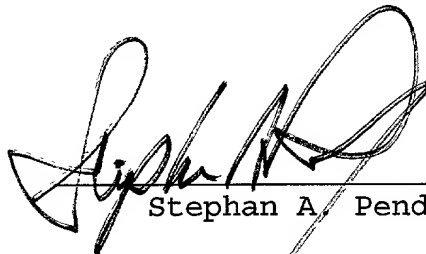
Attorney Docket: 2368/098

German-language document identified with Attorney reference  
paj043.

I hereby declare that all statements made herein of my own  
knowledge are true and that all statements made on information  
and belief are believed to be true; and further that these  
statements were made with the knowledge that willful false  
statements and the like so made are punishable by fine or  
imprisonment, or both, under Section 1001 of Title 18 of the  
United States Code, and that such willful false statements may  
jeopardize the validity of this application and of any patent  
issuing thereon.

Date:

11-10-99



Stephan A. Pendorf

U.S. Application No.:  
VERIFICATION STATEMENT

Attorney Docket: 2368/098

EXPRESS MAIL CERTIFICATE

"EXPRESS MAIL" MAILING LABEL NUMBER: EL435909438US

DATE OF DEPOSIT: November 11, 1999

I HEREBY CERTIFY that the foregoing VERIFICATION STATEMENT PURSUANT TO 37 C.F.R. §1.68 along with English language translation is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated and is addressed: **ATTN: BOX PATENT APPLICATION, Commissioner of Patents and Trademarks, Washington, D.C. 20231.**

The Commissioner is hereby authorized to charge any additional fees which may be required at any time during the prosecution of this application without specific authorization, or credit any overpayment, to Deposit Account Number 16-0877.

  
Sherri A. Campbell



## CONTINUOUSLY CONDUCTIVE UNIPOLAR CANNULA FOR ANESTHESIA

The invention concerns a continuously conductive unipolar cannula for anesthesia.

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A continuously conductive unipolar cannula for anesthesia produced by the company Pajunk GmbH, D-78187, Geisingen, Germany is known, which has an electrically conductive cannula tube, the tube having an electrically insulated outer covering which extends from the proximal body part out to the distal tip of the cannula tube and leaves exposed the distal tip in its distal end area. In the area of the proximal body part, the cannula tube is electrically contacted with a connector, which can be connected to an electro-stimulation device via a socket or jack. The distal tip of the cannula tube is either provided with a facet cut or is designed as a so-called Sprotte tip as disclosed in DE 30 20 926 C2.

In this known unipolar cannula, the connector for electro-stimulation and an injection hose for the anesthetic are provided introduced axially parallel next to each other in the proximal end face of the body part of the cannula tube. The unipolar cannula can be placed exactly in the nerve sheath with its distal tip using electro-stimulation, in order to then be able to apply the anesthetic via the feed hose precisely on the nerve.

In the continuously conductive anesthesia, a catheter is placed in the nerve sheath, in order to be able to introduce anesthetic over a longer period of time. In order to introduce a catheter

- 1 -

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11-11-99  
DATE SIGNATURE Shirley A. Gentry

using the known unipolar cannula, a plastic introducer cannula is pulled over the cannula tube, which is placed under electro-stimulation by means of the unipolar cannula. As soon as the plastic introducer cannula is in place, the unipolar cannula is withdrawn and then the catheter can be introduced through the plastic introduction cannula.

It is further known from DE 36 43 235 C1 and DE 37 12 869 C2, to design a cannula with Sprötte-tip, such that through this cannula itself a catheter can be introduced in place. For this, a ramp or guide is formed in the inside of the distal tip of the cannula tube, which leads to a side outlet opening. A catheter introduced proximally in the cannula tube is led out of the cannula tube via this ramp through the side outlet opening. This cannula is suitable for the placement of a catheter without a supplemental introducer cannula. An electro-stimulation is, however, not possible with this known cannula. Accordingly, this cannula is not provided with an electrical connection for electro-stimulation.

The invention is concerned with the task, of providing a unipolar cannula for the continuous conduction anesthesia, which through simple construction and simple operation unites the placement of the catheter with the advantage of the electro-stimulation.

This task is inventively solved by the unipolar cannula with the characteristics of Claim 1.

Advantageous embodiments and further developments of the invention are set forth in the dependent claims.

The inventive unipolar cannula can be placed or located with the help of electrical nerve stimulation. The outer insulating covering of the cannula tube, which leaves only a very small, almost pinpoint area of the tip free, makes possible an extraordinarily precise placement of the tip. The unipolar cannula can itself be used for the guided introduction of the catheter, for which the body part positioned at the proximal end of the cannula tube exhibits an introduction opening, which leads axially aligned into the cannula tube. The connection for electro-stimulation is introduced through the side of the body part and contacts the outside of the electrically conductive cannula tube. The connection thus does not impede or constrict therewith the axial inlet opening of the body part. After the placement of the unipolar cannula with the help of electro-stimulation, the catheter can be introduced through the cannula tube, without any requirement that the position of the unipolar cannula must be changed or other measures be taken. Preferably, a releasable or removeable connection is formed with the body part at the introduction opening, preferably a luer-lock connection. At this connection, an injection hose can be connected if desired, for injection of an initial or a short duration anesthetic. Likewise, a needle can be connected to the releasable connection, for injection of an anesthetic or also for fluids for aspiration for position control. The possibility of using the body part both for the alternative connection of an injection hose or a needle as well as for introduction of the catheter makes the unipolar cannula extremely versatile. This

versatility is achieved using an extremely simple and economical design. The manipulation of the unipolar cannula is likewise extremely simple, since the cannula can be employed without changing the position both for the injection or aspiration as well as for the introduction of the catheter. The axially aligned connection of a needle at the proximal body part makes possible also the carrying out of the nerve block with a one-hand technique.

The needle of the cannular tube can be designed with a facet cut, so that the outlet opening is formed by the diagonal cut surface slanted with respect to the cannula axis. In this embodiment, the catheter exits out of the distal needle axially aligned with the cannula tube. This design is suitable, for example, for the continuous blockage of the interior ischiadicus, for the positioning of a distal ischiadicus catheter, or for the seating of a psoas compartment block.

Likewise, the distal tip of the cannula tube can be designed as a Sprotte-tip wherein the catheter, which is introduced through the cannula tube, is guided through the side outlet openings behind the tip by means of a ramp. The catheter thereby exits at an angle of approximately  $30^{\circ}$  to the cannula axis. This is of advantage in the anesthetic technique, in which a penetration or piercing essentially parallel to the nerve is not possible. This design of the unipolar cannula is employed, for example, in the interscalenary plexus blockage, the vertical-infraclavical plexus blockage, the ischiadicus blockage, and the blockage of the nervus suprascapularis.

In the following, the invention will be described in greater detail on the basis of the embodiments shown in the drawing. There is shown.

- 5 Fig. 1 a view of the unipolar cannula in a first embodiment,
- Fig. 2 an enlarged vertical section of this unipolar cannula, and
- 10 Fig. 3 an axial section corresponding to Fig. 2 of a second embodiment of the unipolar cannula.

Figs. 1 and 2 show a first embodiment of the unipolar cannula.

15 This cannula includes an electrically conductive cannula tube 10, which is preferably formed of steel. Depending upon the model, the cannula tube 10 has a length of from 25 to 200mm and a diameter of 0.5 to 1.0mm. In the illustrative embodiment of Figs. 1 and 2, the distal end of the cannula 10 is cut or ground with a facet cut 12 less than 45° to the axis of the cannula tube 10, so that a distal tip 14 is formed. The outer surface of the cannula tube 10 is covered with an electrically conductive plastic. The covering extends from the proximal end of the cannula tube 10 out to the distal tip 14 and leaves free only the distal end area 16 of the tip 14 with a length of maximally approximately 1mm, in which the metal of the cannula tube 10 is exposed.

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The proximal end of the cannula tube 10 is positioned co-axially in a body part 18 of plastic and is adhered therewith via a

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hardening adhesive 20. The body part 18 exhibits an essentially cylindrical shape through which a borehole extends co-axially. In the distal area, the inner diameter of this borehole corresponds to the outer diameter of the cannula tube 10 seated in this borehole. The cannula tube 10 projects with its proximal end axially approximately into the middle of the body part 18. In the area of the proximal end of the cannula tube 10, the inner diameter of the body part 18 widens, so that between the inner wall of the body part 18 and the cannula tube 10 a ring gap remains free. In the area of this ring gap, a cylindrical connection socket or jack 22 in electrically conductive contact is pressed against the metallic cannula tube 10. A conductive wire 24 of a stranded conductor 26 is soldered to this metallic connection junction 22. The non-insulated wire 24 runs in the area in which it is soldered with the connection junction 22 axially parallel to the cannula tube 10 in the distal direction. The insulated stranded conductor 26 then bends away at a right angle from this axially parallel direction and extends radially through the body part 18 towards the outside. The opening of the body part 18, through which the connection stranded conductor 26 exits, is filled with a hardening adhesive 28.

The ring gap between the inner wall of the bore of the body part 18 and the proximal end of the cannula tube 10 with the connection socket or jack 22 and the wire 24 is filled with a hardening plastic 30.

The plastic 30 forms an inlet funnel 32, which connects co-axially to the proximal end of the cannula tube 10 and widens

from the inner diameter of the cannula tube 10 in proximal direction to the diameter of the internal bore of the body part 18. Connected with this introduction funnel 32 in the axially proximal direction is the section of the body part 18 designed as luer-lock connection 34, which axially aligns with the cannula tube 10.

On the free end of the stranded connector 26, a plug-in connector junction or jack 36 is provided, with which the unipolar cannula can be plugged into an electrical nerve stimulator. The nerve stimulator sends out electrical voltage impulses of a few milliamps, which are conducted to the exposed distal end area 16 of the tip 14 through the stranded conductor 26, the wire 24, the connector junction 22, and the cannula tube 10, in order to emits an electrical nerve stimulation for localization of the distal tip 14.

On the outer circumference of the body part 18, grip flanges 38 are provided. An indicator notch 40 in one of the grip flanges 38 makes it possible to recognize the angled position of the facet cut 12.

In order to place the unipolar cannula, this is connected by means of the plug-in connector 36 to a nerve stimulator. The cannula tube 10 is stuck into the nerve sheath via the cut tip 14, whereby the respective position of the tip 14 can be controlled via the electro-stimulation. If the distal tip 14 of the cannula tube 10 is in place, then an injection hose can be connected to the Luer-lock connection 34 by means of a Luer-lock connector 42, in order to introduce an anesthetic via the

cannula tube 10. Alternatively, a needle can be connected to the Luer-lock connection 34 in order to control the position of the distal tip 14 by aspiration or in order to inject an anesthetic through this tip. If a catheter is to be placed for a long term anesthesia, so this is - in certain cases after disconnection of the injection hose or the needle - axially introduced through the Luer-lock connection 34, whereby the inlet funnel 32 of the catheter tip leads into the cannula tube 10. The catheter tip passes axially out through the open distal end of the cannula tube 10 and is brought into the desired position. If the catheter is in place, so the unipolar cannula can be pulled out from the catheter from the back, whereby the catheter remains in its position.

Fig. 3 shows a further embodiment of the unipolar cannula. As far as this corresponds with the previously described embodiment, the same reference numbers are employed and reference is made to the above description.

In contrast to the embodiments of Figs. 1 and 2, the distal tip 14 of the unipolar cannula of Fig. 3 is designed as a Sprötte-tip, as this is described in DE 36 43 235 C1. The distal tip 14 is designed as a closed-arched conical needle. Along the side behind the conical opening there is an outlet opening 44. The tip 14 is filled with a hardenable plastic 46, so that a ramp is formed on the inside of the cannula tube 10, which deflects the catheter tip out of the axial direction as it is slid distally towards the front in the cannula tube 10, so that the catheter exits from the side of the outlet opening 44 at an angle of approximately 30° to the axis of the cannula tube 10. The



cannula tube 10 is covered with insulation up to the conically-arched tip 14 so that also here only a distal end area 16 of the tip 14 with a maximal length of 1mm is exposed.

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REFERENCE NUMBER LIST

10 Cannula tube  
12 Facet cut  
5 14 Distal tip  
16 End area  
18 Body part  
20 Adhesive  
22 Junction Box  
10 24 Wire  
26 Multi-stranded conductor  
28 Adhesive  
30 Plastic  
32 Inlet funnel  
34 Luer-lock connection  
36 Plug-in connector  
38 Grip flange  
40 Marking groove  
42 Luer-lock connector  
20 44 Outlet opening  
46 Plastic ramp

## PATENT CLAIMS

1. Continuously conductive unipolar cannula for anesthesia, with an electrically conductive cannula tube (10), with a distal tip (14) of the cannula tube (10), with an exit opening (12, 44) in the area of the tip (14) for a catheter introduced proximally in the cannula tube (10), with a body part (18) provided at the proximal end of the cannula tube (10), with an electrically insulating outer covering of the cannula tube (10), which extends from the body part (18) out to the tip (14) and which leaves the tip (14) exposed at least in its distal end area (16), and with a connector (22, 24, 26) electrically connected to the cannula tube (10) in the area of the body part (18) for electro-stimulation, wherein the body part (18) includes an inlet opening (32, 34) axially aligned with the cannula tube (10) for guiding, and wherein a conductor (24, 26) runs through the casing of the body part (18) to the circumference of the cannula tube (10).
2. Unipolar cannula according to Claim 1, thereby characterized, that the electrical contacting connection includes a connection junction pressed against the circumference of the cannula tube (10), to which a wire (24) of a multi-strand connector (26) is soldered.
3. Unipolar cannula according to Claim 2, thereby characterized, that the wire (24) lies axially parallel against the cannula tube (10) and the multi-strand

conductor (26) is directed radially through the body part (18) towards the outside.

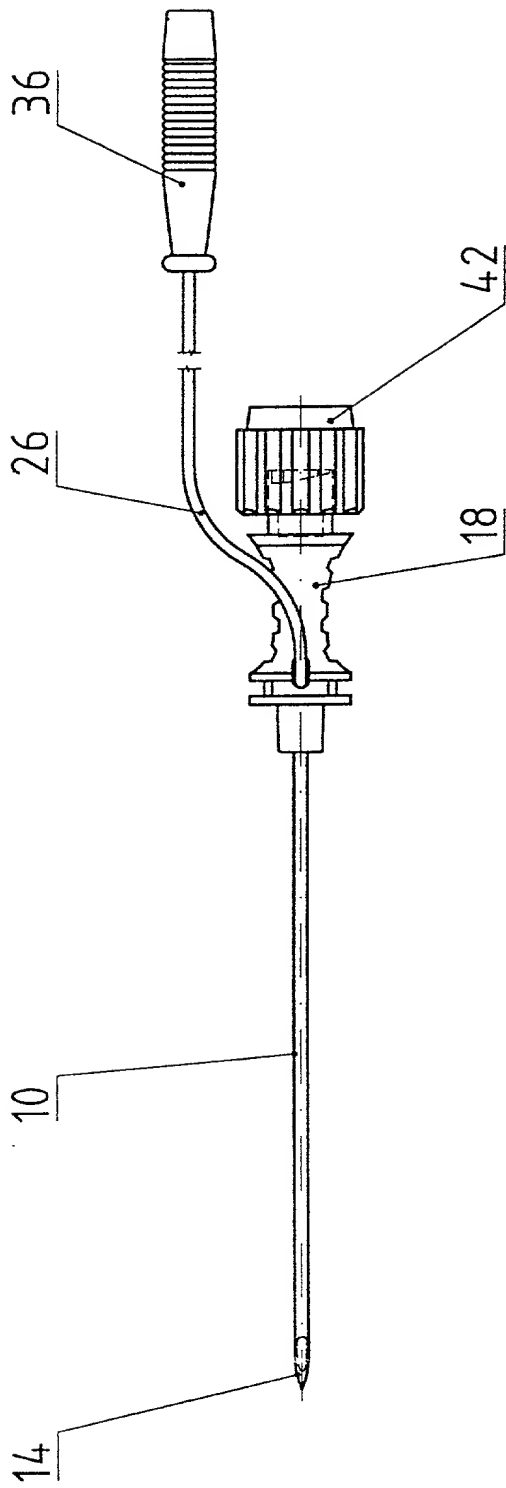
4. Unipolar cannula according to one of Claims 1-3, thereby characterized, that the proximal end of the cannula tube (10) is provided co-axially in the body part (18), and that the ring gap between the proximal end of the cannula tube (10) with the thereto connected electrically contacting connector (22, 24) and an inner wall of the body part (18) is filled with plastic (30).
5. Unipolar cannula according to one of the preceding claims, thereby characterized, that the inlet opening of the body part (18) exhibits a decreasing diameter inlet funnel co-axially against the proximal end of the cannula tube (10).
6. Unipolar cannula according to one of the preceding claims, thereby characterized, that the proximal end of the body part (18) is formed as a Luer-lock connection (34).
7. Unipolar cannula according to one of the preceding claims, thereby characterized, that the exposed end area (16) of the distal tip (14) of the cannula tube (10) has a length of maximally 1mm.
8. Unipolar cannula according to one of Claims 1-7, thereby characterized, that the distal tip (14) of the cannula tube (10) is a facet cut (12).

9. Unipolar cannula according to Claim 8, thereby characterized, that the facet cut (12) is angled at an angle of approximately 45° to the axis of the cannula tube (10).
10. Unipolar cannula according to one of Claims 1-7, thereby characterized, that the distal tip (14) of the cannula tube (10) is formed as a closed conically arched tip with an exit opening (44) provided along the side of the cannula tube proximal behind this tip (so called Sprotte-tip).
11. Unipolar cannula according to Claim 10, thereby characterized, that on the inside of the distal end of the cannula tube (10) a ramp (46) is formed, which guides toward the exit opening on the side.

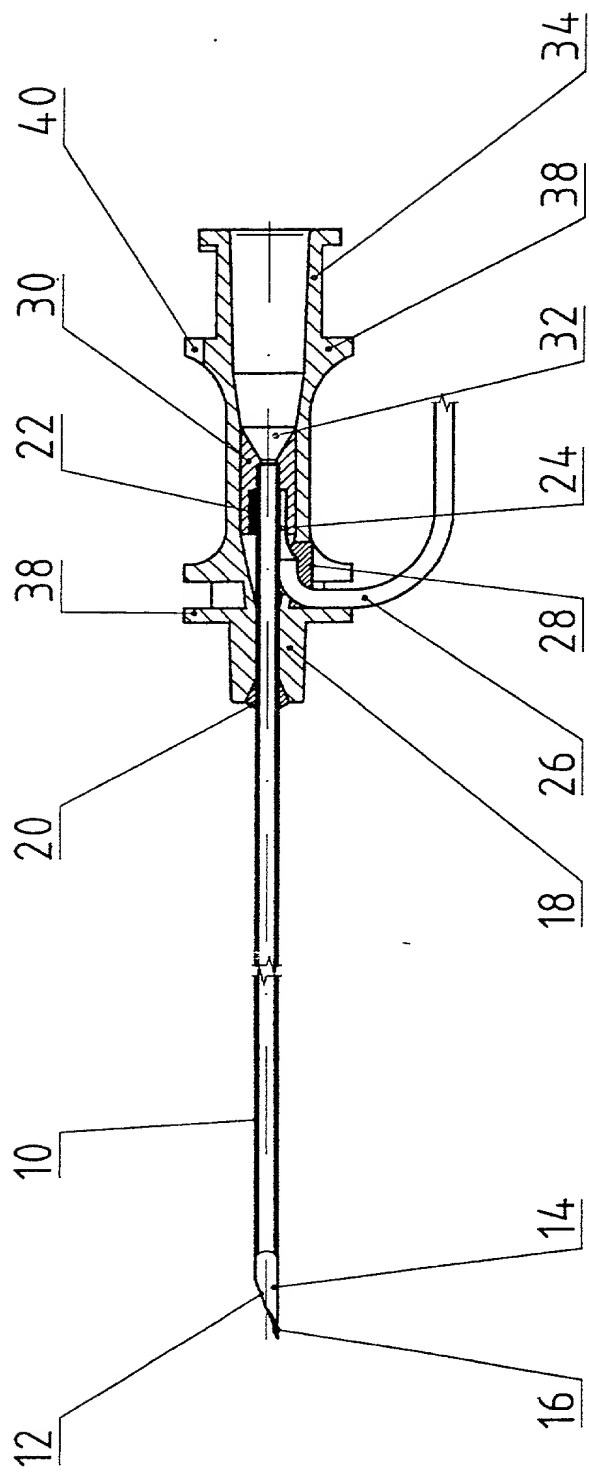
# ABSTRACT

(Fig. 3)

5 A continuously conductive unipolar cannula for anesthesia  
is described with an electrically conductive cannula tube (10),  
with a tip (14) at the distal end and a body part (18) at the  
proximal end. The cannula tube (10) is provided with an outer  
electrically insulating covering, which leaves exposed only an  
end area (16) of the distal tip (14). In the area of the body  
10 part (18), an electrically contacting connection (22, 24, 26)  
for electro-stimulation is provided, which is provided radially  
on the outer circumference of the cannula tube (10). The body  
part (18) includes a guide inlet opening (32, 34) axially  
aligned with the cannula tube (10), through which a catheter can  
be introduced in the cannula tube (10). Alternatively, an  
injection hose or a needle can be connected to the body part  
(18).

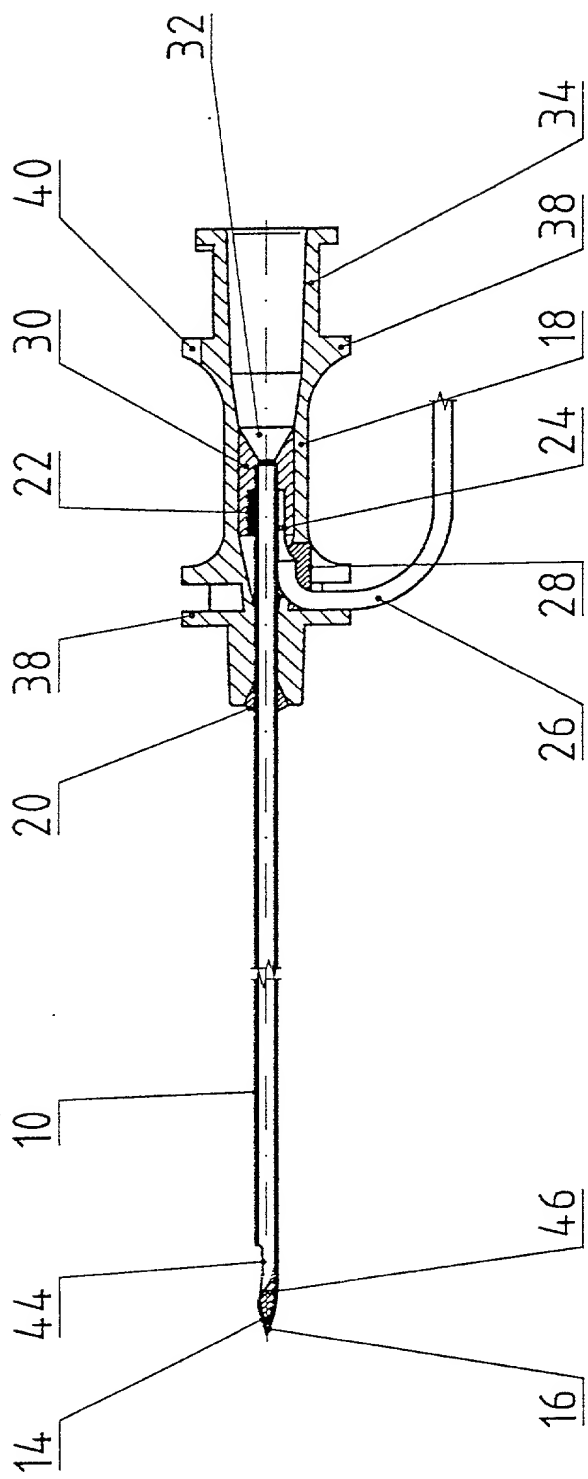


Figur 1



Figur 2





Figur 3